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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,548	01/16/2002	John Austin Burns	38-21(51450)	7713

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MONSANTO COMPANY
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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,548

Applicant(s)

BURNS ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed 6/6/2003 has been entered.
Claims 1-7, and 9-20 are pending.
Claims 8 and 21-23 have been canceled.
2. Claims 1-7 and 9-20 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Indefiniteness

5. Claims 1-7, 9-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Rejection includes dependent claims.

In claim 1, 6th line, the word "explants" should be changed to --explant-- for proper antecedent basis.

In claim 13, the metes and bounds of "commercial variety or elite line" has not been defined. It is not clear what constitutes a commercial variety or when is a line considered 'elite'. It is suggested that "commercial variety or elite line" be deleted.

In claims 15-17, Applicant is using the word "explant" to mean parts of a plant other than what Applicant originally defined the term to mean in claim 1. In claim 16 and 17, Applicant defines the explant to include a node, the cotyledonary node, or part thereof which is different

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than the original definition and as such, it is unclear what is the exact meaning of "explant" or "explant thereof".

Obviousness

6. Claims 1-7, 9-12, 16, and 18 remain rejected and claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bajaj et al (1986, Indian Journal of Experimental Biology 24:581-583, listed in IDS) taken with deSilva et al (1976, HortScience 11(6):569-570). This rejection is maintained for the reasons of record set forth in the Official action mailed 12/4/2002. Applicant's arguments filed 6/6/2003 have been fully considered but they are not persuasive.

Applicants contend that Bajaj et al do not suggest other compounds that can be used to produce multiple shoots. Applicants also contend that deSilva et al do not teach the use of an apical dominance inhibitor such as dikegulac in plant tissue culture and that there is no reasonable expectation of success based upon the teachings of deSilva et al.

The Office contends that deSilva et al teach the use of dikegulac to chemically induce the formation of multiple shoots when sprayed on Azalea plants and one skilled in the art would expect that dikegulac would have the same physiological effect on plants *in vivo* as plants/explants *in vitro*. Given the function of dikegulac to produce multiple shoots from an Azalea, and absent evidence to the contrary, it would have been obvious to incorporate the shoot-multiplication-effect of dikegulac into culture media so as to increase the number of shoots formed off of any given callus or plant tissue with a reasonable expectation of success.

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7. Claims 1-7, 9-13, 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bajaj et al (1986, Indian Journal of Experimental Biology 24:581-583, listed in IDS) in view of George (1993, Plant Propagation by Tissue Culture, Exegetics Ltd, Great Britain, page 469, listed in IDS).

The claims are drawn to a method for regenerating a plant comprising culturing an explant comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol and rooting the cultured explant to produce a plant. The claims are further limited to include an auxin wherein the auxin is IAA and the medium also includes a cytokinin wherein the cytokinin is BA or ZR and the plant is a cotton plant.

Bajaj et al teach a method of regenerating a cotton plant comprising culturing cotton shoot tips on MS medium comprising IAA and BA and subsequently producing plants.

Bajaj et al do not teach the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol.

George teaches the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol that are used in culture media to increase the number of shoot meristems that are produced from a given explant. George also teaches using 500 to 1000 mg/l dikegulac.

Given the recognition of those of ordinary skill in the art of the value of regenerating cotton plants using tissue culture techniques as taught by Bajaj et al, and given the value of adding one of the apical dominance inhibitors, dikegulac, methyl laurate or octadecyl-polyethoxyethanol to culture media to increase the number of shoot meristems that are regenerated from tissue explants as taught by George, it would have been obvious to include one

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of the apical dominance inhibitors in the method of Bajaj et al so as to increase the number of cotton shoot meristems that are produced from a single explant. In addition, Applicant has claims drawn to the use of zygotic embryos as explants. Given the wide use of all plant parts including zygotic embryos, as explants, it would have been routine experimental procedure to substitute one plant with another as an explant. And lastly, Applicant claims a concentration of dikegulac between 5-5000 mg/L, which is such a wide range that one skilled in the art would routinely use at least one concentration within the range as claimed with a reasonable expectation of success.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

8. Claims 1-2, 4-7, 9-11, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohamed-Yasseen et al (1990, PGRSA Quarterly 18(4):203-210) in view of George (1993, Plant Propagation by Tissue Culture, Exegetics Ltd, Great Britain, page 469, listed in IDS).

The claims are drawn to a method for regenerating a plant comprising culturing an explant comprising a shoot meristem or primordia on a medium comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol and rooting the cultured explant to produce a plant. The claims are further limited to include a cytokinin wherein the cytokinin is BA or ZR and the plant is a soybean plant.

Mohamed-Yasseen et al teach a method of regenerating a soybean plant comprising culturing soybean cotyledon pieces, shoot apices, and cotyledonary nodes on Gamborg's, or MS media comprising BA and subsequently producing plants.

Mohamed-Yasseen et al do not teach the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol.

George teaches the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol that are used in culture media to increase the number of shoot meristems that are produced from a given explant. George also teaches using 500 to 1000 mg/l dikegulac.

Given the recognition of those of ordinary skill in the art of the value modifying soybean plants using genetic engineering which requires a protocol for regenerating soybean plants using tissue culture techniques as taught by Mohamed-Yasseen et al, and given the value of adding one of the apical dominance inhibitors; dikegulac, methyl laurate or octadecyl-polyethoxyethanol to culture media to increase the number of shoot meristems that are regenerated from tissue explants as taught by George, it would have been obvious to include one of the apical dominance inhibitors in the method of Mohamed-Yasseen et al so as to increase the number of soybean shoot meristems that are produced from a single explant. In addition, Applicant has claims drawn to the use of zygotic embryos as explants. Given the wide use of all plant parts including zygotic embryos, as explants, it would have been routine experimental procedure to substitute one plant with another as an explant. And lastly, Applicant claims a concentration of dikegulac between 5-5000 mg/L, which is such a wide range that one skilled in the art would routinely use at least one concentration within the range as claimed with a reasonable expectation of success.

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Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

9. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umbeck (April 1991, U.S. Patent 5,004,863) in view of George (1993, Plant Propagation by Tissue Culture, Exegetics Ltd, Great Britain, page 469, listed in IDS).

The claims are drawn to a method for regenerating a transgenic plant comprising providing an explant of a plant, introducing a recombinant DNA vector into the explant, culturing the transformed explant in a media comprising an apical dominance inhibitor dikegulac, methyl laurate or octadecyl-polyethoxyethanol and rooting the transformed explant to produce a transgenic plant.

Umbeck teaches a method of transforming and regenerating cotton plants comprising growing cotton plants in vitro, culturing hypocotyl explants on medium, inoculating explants with *Agrobacterium*, selecting transformed callus and regenerating whole plant (columns 7-9, Example 1).

Umbeck does not teach the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol.

George teaches the apical dominance inhibitors dikegulac, methyl laurate or octadecyl-polyethoxyethanol that are used in culture media to increase the number shoot meristems that are produced from a given explant. George also teaches using 500 to 1000 mg/l dikegulac.

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Given the recognition of those of ordinary skill in the art the value of regenerating transgenic plant material as taught by Umbeck, and given the value of adding one of the apical dominance inhibitors; dikegulac, methyl laurate or octadecyl-polyethoxyethanol to culture media to increase the number of shoot meristems that are regenerated from tissue explants as taught by George, it would have been obvious to include one of the apical dominance inhibitors in the method of Umbeck so as to increase the number of shoot meristems that are produced from a single explant. Applicant's claims are drawn to transforming the plant tissue either before or after the multiplication step using an apical dominance inhibitor. Transforming tissue either before or after the multiplication step is an obvious design choice in view of the lack of criticality.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

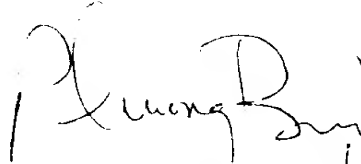
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

August 25, 2003


PHUONG T. BUI
PRIMARY EXAMINER 8/25/03